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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/025,423	12/18/2001	Ronald N. Zuckermann	16141.003	6469

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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05/18/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No.		Applicant(s)	
	10/025,423		ZUCKERMANN ET AL.	
	Examiner		Art Unit	
	T. D. Wessendorf		1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/6/06; 2/22/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-17, 21, 25-29 and 33-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-17, 21, 25-29 and 33-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Election/Restrictions***

Applicant's election of the species presented in Figure 3; the species with respect to formula I, as follows: Ra is a lipid moiety connected to a linker moiety; Rb is selected from the group consisting of alkyl, and aralkyl, wherein alkyls are substituted with amino and guanidino groups and aralkyl is substituted with an alkoxy group; R1 and R2 are hydrogen atoms; R~ is NH2 group; and m=9; the elected species with reference to formula II as follows: Ra is a lipid moiety connected to a linker moiety; Rb is an amino substituted alkyl or guanidino substituted alkyl (cationic moieties); Rb2 and Rb3 are alkoxy substituted aralkyls (non-cationic moieties); R1 and R2 are hydrogen atoms; R is NH2 group; and n=3 in the reply filed on 2/22/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Status of Claims

Claims 13-17, 21, 25-29 and newly added 33-37 are pending and under examination in this application.

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Withdrawn Rejection

In view of the amendments made on 6/6/2006 to the claims, the rejection under the first paragraph and second paragraph of 35 U.S.C. 112 has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-17, 21, 25-29 and 33-37, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (This is a new matter rejection).

1. The claimed "providing a library of peptoids having a plurality of unknown sequences and having the general formula I" is not supported in the as-filed specification. The as-filed

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specification does not recite that the library of peptides have a plurality of unknown sequences with the general formula I.

Applicants cite page 8, paragraph 4; page 15, 3rd paragraph and Fig. 2 of the instant specification for support.

None of the cited sections recite an **unknown sequences with the general formula 1**. The cited section discloses a different concept from the claim.

2. Newly added claim 33 having the recited formula II is not supported in the original disclosure.

Applicants state that support can be found in Figs. 1C, 1D, 3 and claim 24.

A review of Figs. 1C, 1D and 3 does not reveal a subgenus of formula II, rather a specific formula/structure. Also, claim 24 recites the generic claim formula I, not the present subgenus of formula II.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-17, 21, 25-29 and 33-37, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for

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failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 13 (i), as amended, is unclear and confusing as to the contradictory statement that the library of peptoids has a plurality of unknown sequences and in the same breath has the general formula I. It is unclear in what sense it is unknown when Formula I recites the sequences of each of the species encompassed by the generic formula 1 (appropriately enough to enable identifying a species in the library).

Step (ii) is unclear as to how it is determined that a "plurality" of the unknown peptoids in the library is contacted with the oligonucleotide. The amended claim is confusing.

B. Non-sequitur for "said terminal peptoids" in claim 33. Is the formula terminal to the N or C terminus? Furthermore, "n" is inconsistent with the base claim "m". The base claim m recites an integer of 2 to about 50, which is repeated by the n variable of 2 to 16. Furthermore, the definitions of Rb1, Rb2 as non-cationic moiety broaden the base claim 1, which defines the Rb variables with specificity i.e., as an alky, aralkyl and so on. The amended and added claims do not make sense.

C. Claim 34 is unclear as to the difference(s) of one cationic moiety, given no structure for said moiety, especially in the base claim, which does not identify said cationic moiety.

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Lack of antecedent basis of support for the term "cationic moiety".

D. Claim 35, which is drawn to a **method of making** the library by a mix-and-split protocol, does not further limit the method of identifying recited in claim 13. It is not clear as to the "protocol" used in the mix-and-split method.

E. Claim 37, "method" of spectrography does not positively recite the method steps, especially absent positive antecedent basis of support from the base claim 13.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

Claims 13-17, 21 and 24-29, as amended, are rejected on the ground of nonstatutory double patenting over claims 1-2 of U. S. Patent No. 6677445 ('445 Patent) since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent for reasons reiterated below.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: a peptoid-oligonucleotide mixture useful for

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a method of transfecting cell. (See col. 5, line 65 up to col. 7, line 45 of the '445 Patent).

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Response to Arguments

Applicants submit that the claims to these compositions do not render obvious the claim to a "'method of identifying peptoids". The Applicants also point out that it is not appropriate to rely on written description of a patent for an obviousness-type double patenting rejection. Only inventions as claimed can be evaluated, with the written description serving merely as a dictionary for claim interpretation. "Any obviousness-type double patenting rejection should make clear: (A) The differences hereon the inventions defined by the conflicting claims - a claim in the patent compared to claim in the application; and 03) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent. When considering whether the invention defined in a claim of an application is an obvious

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variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art" (MPEP, section 804).

In reply, the rejection is based on a claim per claim comparison between the ('445 Patent) and the instant claims. The claimed composition of the ('445) Patent is the same composition used in the instant method claim, which is an obvious use for the claimed composition. Read in the light of the specification as to the use of a composition, the ('445 Patent) discloses the composition used in the instant method, if not, the only utility of the composition.

The claimed subject matter, if allowed, would improperly extend the "right to exclude" already granted in the patent simply because applicants failed to claim the instant subject matter in the '445 Patent. ***There is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent.*** See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

Newly added claim 33 is rejected under 35 U.S.C. 102(e) as being anticipated by Liotta (USP 6,153,596). (This rejection is based on the interpretation that the peptoids has a known sequence as shown by Formula II).

The claimed method of identifying peptoids in a library of different sequence peptoids comprising of the recited steps (i)-(iv) having the formula II is fully met by the method of Liotta. Liotta discloses the same method of transfecting cell with an oligonucleotide by administering peptoids as taught at col. 7, line 54 up to col. 18, line 11, specifically col.14, lines 40-56. The formula of the peptoids is disclosed at col. 10, line 26 up to line 16, line 39.

Claim Rejections - 35 USC § 103

Claims 13-17, 21, 25-29, 33-34 and 36-37, as amended and newly added, are rejected under 35 U.S.C. 103(a) as being unpatentable Liotta (USP 6,153,596) in view of Murphy (PNAS).

Liotta is discussed above. Liotta does not disclose peptoids of general formula I as recited in claim 13, for example. However, Murphy discloses at page 1518, RESULTS and DISCUSSION section up to page 1521, col. 1 that peptoid with lipid derivatized at the N-end results in a highly efficient

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transfection agent. The ability to derivatize a defined site in the peptoid side chain will allow for the controlled synthesis of delivery vehicles modified with targeting ligands.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the peptoid of Murphy in the method of Liotta. The advantages disclosed by Murphy, above would provide the motivation to do such substitution.

Claim 14 is obvious in view of the disclosure of Murphy as to the use robotic synthesizer, page 1517, col. 2.

Claim 26 is obvious in view of the teachings of Liotta as to the advantage in the use of sterol as a side group e.g., sterol tethered in the peptoid chain. See col. 12, lines 20-30 and col. 16, lines 29-39.

Claim 35 is obvious over the teachings of Murphy at page 1517 under Materials and Methods section, which refers to the Zuckermann reference, for example, as similarly done by applicants at page 17, third paragraph.

Claim 37 is obvious over the disclosure of Murphy at page 1518, col. 1.

The elected species are obvious over the disclosure of Murphy at e.g., page 1519, Table 1 up to page 1521.

Response to Arguments

Applicants acknowledge that both Liotta and Murphy are using peptoids of known sequence for cell transfection. But argue that the instant claims provide a plurality of peptoids of unknown sequence, screen for cell transfection, and only upon successful transfection determine the chemical identity of the transfecting peptoid. It should be noted that the Applicants' invention as described in the specification is directed towards a transfecting agent discovery method. As a discovery method it is substantially different from the methods of Liotta and Murphy.

In response, as best as the claim can be interpreted, given the general formula I, the instant claimed sequences have also the known sequences as the prior art. With regards to Applicants' arguments with respect to the discovery method described in the specification, it is well settled that applicants cannot import limitations in the specification to the claims. As applicants stated above, written description serves merely as a dictionary for claim interpretation. Furthermore, it is unclear as to the discovery method applicants are alluding to especially since the prior art discloses similar, if not the same method, as claimed.

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Applicants state that as described in the Applicants' specification, the instant type of library can be synthesized by, for example, a mix-and-split protocol, which is superior to parallel synthesis. The instant library with unknown sequences cannot be attained by the synthetic procedures of Liotta and Murphy.

In reply, as stated applicants cannot import limitations in the specification into the claims and the specification is used "merely as a dictionary" for claim interpretation. Applicants' arguments with respect to the synthesis of the instant peptides are not commensurate in scope with the claims which recite a screening method and not a method of making or synthesizing peptoids. Nonetheless, the mix-and-split method of library synthesis is well known in the art, as taught by Murphy.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will

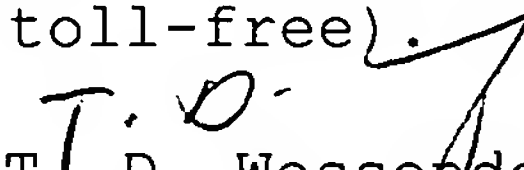
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expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on (571) 272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 10, 2007